

REMARKS

Claims 28-37 are all the claims pending in the application, prior to the present Amendment.

Claim 30 has been rejected under the second paragraph of 35 U.S.C. § 112 as being indefinite.

The Examiner states that the antecedent basis for the term “the coenzyme Q” in claim 30 is unclear because it is not clear whether the phrase in claim 30 refers to the reduced coenzyme Q, the oxidized coenzyme Q or both.

In response, applicants have amended claim 30 by deleting the term “coenzyme Q” and by reciting that n is 10.

In view of the above, applicants request withdrawal of this rejection.

Claims 28-35 are rejected under 35 U.S.C. § 102(b) as anticipated by Hidaka et al, as evidenced by Merriam - Webster Collegiate Dictionary.

In addition, claims 28-30 and 32-36 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Fujii et al (WO 2002/092067), citing to U.S. Patent Application No. 2004/0115181 for an English translation, in view of Staub et al.

Further, claims 28-30 and 32-36 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Fujii et al (WO 2002/092067), citing to U.S. Patent Application No. 2004/0115181 for an English translation, in view of Wilson et al.

Applicants submit that Hidaka et al, Merriam - Webster Collegiate Dictionary, Fujii et al (WO 2002/092067), citing to U.S. Patent Application No. 2004/0115181 for an English

translation, Staub et al and Wilson et al do not disclose or render obvious the subject matter of the presently claimed inventions and, accordingly, request withdrawal of these rejections.

The present invention as set forth in claim 28 is directed to a method for reducing fatigue in animals in the state of fatigue, which comprises administering, to said animals, a fatigue reducing agent comprising reduced coenzyme Q represented by formula (1) of claim 28 as an active ingredient.

The present invention as set forth in claim 29 is directed to a method for reducing fatigue in animals by administering a fatigue reducing agent, and recites that the fatigue reducing agent comprises the reduced coenzyme Q of formula (1) and oxidized coenzyme Q of formula (2).

Applicants have amended claims 28 and 29 to recite that the fatigue is physical exhaustion caused by exercise or fatigue caused by aging. Support for this amendment can be found in the present specification at page 1, last two lines to page 2, line 2.

There are two kinds of fatigue, the one physiological, the other pathological. Physiological fatigue manifests in a healthy individual without underlying diseases when the amount of activity exceeds a certain level and it can be naturally relieved by rest. On the other hand, pathological fatigue manifests in patients with a physical disorder, such as cancer and AIDS, a mental disorder such as depression, and sleep disorder and/or a continual weariness, such as chronic fatigue syndrome, and it cannot be naturally relieved by rest alone. Namely, "fatigue" occurs in a wide variety of situations, which are described in the cited Merriam-Webster and Staub et al documents.

It is technically known that the effects on fatigue and methods of dealing with fatigue vary depending on the nature and cause of the fatigue. In the present invention, "reducing fatigue" aims to maintain one's stamina and good health in daily life, as described in the Abstract, Background Art and the like in the present specification. In other words, the object of the present invention is reduction of physiological fatigue, rather than reduction of extreme fatigue due to severe disease, or pathological fatigue. Hidaka et al and Fujii et al merely disclose that reduced coenzyme Q is effective for specific diseases.

The method of the present invention does not aim at reducing pathological fatigue caused by the diseases recited in Hidaka et al and Fujii et al. In addition, Hidaka et al and Fujii et al do not teach that pathological fatigue caused by diseases can be reduced by administration of reduced coenzyme Q, even though the skin diseases disclosed in Hidaka et al may be treated by dermal application of reduced coenzyme Q. Therefore, Hidaka et al do not inherently disclose the fatigue-reducing property disclosed in the present invention.

As mentioned above, inasmuch as the "physical exhaustion caused by exercise or fatigue caused by aging", which is the target in the present invention, is completely different in the cause and mechanism from the pathological severe fatigue due to the diseases recited in Hidaka et al and Fujii et al, and inasmuch as Hidaka et al and Fujii et al do not teach that pathological severe fatigue can be decreased by reduced coenzyme Q, the effect of the present invention cannot be arrived at from the teachings of Hidaka et al and Fujij et al.

Wilson discloses that patients with heart failure are limited by exertional fatigue during both normal daily activities and maximal exercise. Therefore, exertional fatigue in heart failure

patients disclosed in Wilson can be clearly distinguished from the "physiological fatigue" in healthy people during daily life and exercise.

In view of the above, applicants submit that Hidaka et al, Merriam - Webster Collegiate Dictionary, Fujii et al (WO 2002/092067), citing to U.S. Patent Application No. 2004/0115181 for an English translation, Staub et al and Wilson et al do not disclose or render obvious the subject matter of the presently claimed invention and, accordingly, request withdrawal of these rejections.

The Examiner has set forth a number of double patenting rejections over copending applications as follows:

(1) Claims 28-30 and 32-35 have been rejected on the grounds of nonstatutory double patenting as being unpatentable over various claims of U.S. Patent Application Nos. 10/275,882, 11/029,493, 11/315,201, or 11/909,966, each in view of the Merriam - Webster Collegiate Dictionary.

(2) Claims 28, 30 and 32-35 have been rejected on the grounds of nonstatutory double patenting as being unpatentable over various claims of U.S. Patent Application No. 10/505,523 in view of the Merriam - Webster Collegiate Dictionary.

Since the copending applications have not yet issued as patents, applicants defer responding to these rejections.

Claims 28 -36 have been rejected on the grounds of nonstatutory double patenting as being unpatentable over claim 5 of U.S. Patent 6,184,255 to Mae et al or claims 3 to 16 of U.S. Patent 7,015,252 to Fujii et al in view of the Merriam - Webster Collegiate Dictionary.

Mae et al simply disclose that coenzyme Q containing reduced coenzyme Q is superior by oral administration and effective for lack of coenzyme Q. Since there are a wide variety of causes of fatigue, as mentioned above, the treatment or effect of the present invention to reduce "physical exhaustion caused by exercise or fatigue caused by aging" is not obvious from Mae et al or Merriam - Webster.

Further, Fujii et al '252 simply discloses a method for lessening oxidative stress such as caused by disease by administering reduced coenzyme Q. Fujii et al '252 and Merriam - Webster do not disclose or suggest the treatment or effect of the present invention to reduce physical exhaustion caused by exercise or fatigue caused by aging by administering reduced coenzyme Q.

In view of the above, applicants request withdrawal of this rejection.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.116
Application No.: 10/541,020

Attorney Docket No.: Q88147

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

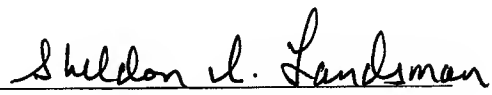
SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: March 16, 2009


Sheldon I. Landsman
Registration No. 25,430